

69. The method of claim 68, wherein said one or more genes is a *fabB* gene.--

### ***Remarks***

Reconsideration of the present application is respectfully requested.

#### ***I. Status of the Claims***

Claims 1-44 have been canceled. Claims 45-69 have been added. Claims 45-69 are pending in the present application.

#### ***II. Support for the Amendment***

The present application is a continuation of parent Appl. No. 08/826,426, filed March 27, 1997, now U.S. Patent No. 5,891,692. As filed, the specification of the parent application reflected that the parent application is a continuation-in-part of provisional U.S. patent application nos. 60/014,330 and 60/025,838. The disclosures of the priority non-provisional applications were merged in the parent non-provisional application. However, the parent non-provisional application is not a "continuation-in-part" of the priority provisional applications.

The MPEP instructs that "[a]n application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a 'continuation-in-part' of the provisional application since the application will have its patent term calculated from its filing date . . . ." See MPEP §201.08. Accordingly, the specification of the present application has been amended to delete reference to the parent application as a "continuation-in-part," and to reflect that the present application is a continuation of the parent application.

Support for new claims 45 and 46 is found, for example, in original claim 15, and in the specification at page 2, last paragraph.

Support for new claim 47 is found, for example, in the specification at page 3, lines 6-9.

Support for new claim 48 is found, for example, in original claim 19, and in the specification at page 2, last two lines to page 3, first two lines.

Support for new claim 49 is found, for example, in original claim 21.

Support for new claim 50 is found, for example, in original claim 20.

Support for new claim 51 is found, for example, in original claim 22.

Support for new claim 52 is found, for example, in original claim 23.

Support for new claim 53 is found, for example, in original claim 24.

Support for new claim 54 is found, for example, in original claim 25.

Support for new claim 55 is found, for example, in original claim 26.

Support for new claim 56 is found, for example, in the specification at page 14, lines 3-4.

Support for new claim 57 is found, for example, in the specification at page 14, lines 3-4, and pages 46-54 (Examples 15 and 16).

Support for new claims 58 and 59 is found in original claim 15, and in the specification at page 2, last paragraph.

Support for new claim 60 is found, for example, in original claim 19, and in the specification at page 2, last two lines to page 3, first two lines.

Support for new claim 61 is found, for example, in original claim 21.

Support for new claim 62 is found, for example, in original claim 20.

Support for new claim 63 is found, for example, in original claim 22.

Support for new claim 64 is found, for example, in original claim 23.

Support for new claim 65 is found, for example, in original claim 24.

Support for new claim 66 is found, for example, in original claim 25.

Support for new claim 67 is found, for example, in original claim 26.

Support for new claim 68 is found, for example, in the specification at page 14, lines 3-4.

Support for new claim 69 is found, for example, in the specification at page 14, lines 3-4, and pages 46-54 (Examples 15 and 16).

No new matter has been added by this amendment.

### ***III. The Inventor Declaration***

The present application is a continuation of parent Appl. No. 08/826,426, filed March 27, 1997, now U.S. Patent No. 5,891,692. A copy of the Declaration and Power of Attorney for Patent Application filed July 25, 1997 in the parent application was apparently filed in the present application on January 8, 1997. At page 8 of the Office Action, the Examiner explained that the copy of the Declaration and Power of Attorney for Patent Application filed in the present application is unacceptable.

A substitute Declaration for Patent Application was filed in the parent application on May 14, 1998, and was accepted. Filed herewith is a copy of the substitute Declaration for Patent Application. Applicants respectfully request that this objection be withdrawn.

**IV. The Rejection For Obviousness-Type Double Patenting Must Be Withdrawn**

Claims 1-44 stand rejected for alleged obviousness-type double patenting over claims 1-16 of U.S. Patent No. 5,891,692. Applicants respectfully traverse this rejection. Claims 1-44 of the present application have been canceled without prejudice to or disclaimer of the subject matter therein. Accordingly, it is believed that the alleged ground for this rejection is moot. Applicants respectfully request that this rejection be withdrawn.

**V. The Rejections Under 35 U.S.C. § 102(b) Must Be Withdrawn**

Claims 1-14 and 29-44 stand rejected as allegedly anticipated by either Ulrich *et al.*, *J. Bact.* 154:221 (1983) ("Ulrich") or de Mendoza *et al.* *Biol. Chem.* 258:2098 (1983) ("de Mendoza"). Applicants respectfully traverse these rejections. Claims 1-14 and 29-44 have been canceled without prejudice to or disclaimer of the subject matter therein.

Neither Ulrich nor de Mendoza teaches the methods of new claims 45-69. Applicants respectfully request that these rejections be withdrawn.

**VI. The Rejection Under 35 U.S.C. § 112, First Paragraph, Must Be Withdrawn**

**A. The Rejection**

Claims 1-44 stand rejected as allegedly not enabled. Applicants respectfully traverse this rejection. Claims 1-44 have been canceled without prejudice to or disclaimer of the subject matter therein. New claims 45-69 have been added. To the extent that this rejection may be applied to claims 45-69, Applicants provide the following remarks.

At pages 4-5 of the Office Action, the Examiner states:

[T]he specification, while being enabling for methods for enhancing the viability of bacteria during low temperature storage or for enhancing transformation efficiency following low temperature storage by transforming bacteria with genes

which increase the percent of unsaturated fatty acids in the cell membrane, does not reasonably provide enablement for other modifications of the bacteria which would result in the properties as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Other than genes which directly increase the percentage of unsaturated fatty acids in the cell membrane, the specification fails to teach how a bacterium will be modified to result in the properties claimed. Other than direct introduction of such genes on plasmids for over-production of the gene product, the specification fails to teach how to increase expression of such genes, especially those located on the bacterial chromosome.

#### ***B. The Standard for Enablement***

The initial burden of proving that a specification is non-enabling is on the Examiner. It is axiomatic that a specification is presumed to be enabling unless the Examiner provides acceptable objective evidence or sound scientific reasoning showing that it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. The Federal Circuit has explained:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

*In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). Thus, under *Marzocchi*, the claims in an application are presumed to be enabled, unless proven otherwise.

Further, it is well-established that some experimentation is permitted, so long as it is not "undue."

**C. *A Prima Facie Case of Non-Enablement Has Not Been Established***

The Examiner has failed to establish a *prima facie* case of non-enablement, because neither objective evidence nor sound scientific reasoning has been presented to show that the claimed invention is not enabled. In fact, in view of Applicants' application and knowledge possessed by one of ordinary skill in the art, the claimed invention is enabled. Applicants have disclosed at least two specific ways to practice the claimed methods. For example, in Example 1, Applicants discuss that the claimed methods could be practiced by cycling bacteria through an unfavorable condition, such as storage at -20°C, and selecting bacteria having the properties recited in the claims. In the detailed description, and in the examples, Applicants discuss that the claimed methods could also be practiced by transforming bacteria with one or more genes that result in an increase in fatty acid content of the bacterial membrane.

Thus, given the knowledge possessed by one of ordinary skill in the art and Applicants' disclosure, the claimed invention is enabled. Because no evidence to the contrary has been presented, this rejection is improper. Applicants respectfully request that this rejection be reconsidered and withdrawn.

**VII. *The Rejection Under 35 U.S.C. § 112, Second Paragraph, Must Be Withdrawn***

Claims 1, 5-7, 9, 15, 19-21, 23, 32, 40 and 44 stand rejected as allegedly indefinite. Applicants respectfully traverse this rejection. The rejected claims have been canceled without prejudice to or disclaimer of the subject matter therein. To the extent that this rejection may be applied to pending claims 45-69, Applicants provide the following remarks.

The Examiner objects to the terms "modifying," "altered" and "unsaturated fatty acid genes." These terms do not appear in claims 45-69. Accordingly, this alleged ground for the rejection is moot.

Applicants respectfully request that this rejection be withdrawn.

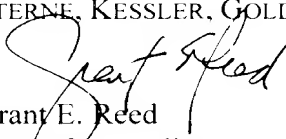
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted.

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